

REMARKS

Reconsideration and allowance of the present application are respectfully requested. Claims 1-77 remain pending in the application. By the foregoing amendment claims 1, 3, 10, 13, 15, 22, 23, 26, 28, 29, 32, 34, 37, 38, 40, 41, 44-47, 56, 59, 62, 64, 71, 72, 75 and 77 are amended.

Applicant notes with appreciation the Examiner's indication on page 8 of the Office Action that claims 23-28, 41-46 and 72-77 contain allowable subject matter. However, it is respectfully submitted that independent claims 1, 40 and 47 are patentably distinct in their present form. The Examiner has failed to recognize significant differences possessed by the presently claimed invention over the documents relied upon in the Office Action.

On page 2 of the Office Action, claims 1-77 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite. To obviate the rejection, claims 1, 3, 10, 13, 15, 22, 23, 26, 28, 29, 32, 34, 37, 38, 40, 41, 44-47, 56, 59, 62, 64, 71, 72, 75 and 77 are amended. Regarding claim 1, Applicants respectfully submit that the steps are distinctly identified as amended. Regarding claims 49 and 50, Applicants respectfully submit that the original claims each recite a distinct subject matter. Withdrawal of the rejection is respectfully requested.

The Garver et al. Patent

On page 4 of the Office Action, independent claims 1 and 47, along with various dependant claims, are rejected under 35 U.S.C §102(b) as being anticipated by U.S. Patent No. 6,263,725 (Garver et al.). This rejection is respectfully traversed.

The Examiner asserts at paragraph 4, page 4 of the Office Action, "Garver et al teach of a method and apparatus for characterizing the stability of colloids ... The

stress factor applied to the colloid is a change in temperature. The light attenuation or light scattering is measured at two or more temperatures to provide a measure of the stability of the dispersion with respect to temperature," and concludes that it is inherent in the method taught by the Garver et al. patent that "the instability of the colloid sample analyzed is manifested by particle agglomeration due to the reduction in the height of the potential energy barrier between the particles." Applicants respectfully disagree with the Examiner's asserted conclusion.

The term "stress factor", as used by the Applicants, is unique to the present application. It is not a common terminology used in the field according to those skilled in the art. Garver et al. does not teach or suggest applying a "stress factor" as the Examiner asserts. The Examiner has misused the term "stress factor" in describing the Garver et al. patent.

Applicants have disclosed methods and apparatus for determining the stability of a sample comprising a dispersion of solid or liquid droplet particles suspended in a liquid carrier (e.g., page 37, lines 8-16). A degradation in stability can be an evolving agglomeration that occurs naturally, e.g., instability within the present "system", but as disclosed, it is accelerated by mildly perturbing the limits of stability to identify inferior dispersions that destabilize prematurely (e.g., page 34, lines 4-11). A colloidal particle component may have a propensity to agglomerate continuously and irreversibly with time, due to the deliberate and precise application of a stress factor (e.g., page 38, lines 1-3). A systematic application of one or more relatively small increments of "stress" onto a particle suspension can systematically lower the inter-particle potential energy barrier height that lends stability to the particles (e.g., page 38, lines 4-13). The result is a steady, progressive increase in the extent of

agglomeration of the particles, monitored as a function of time. The Applicants' disclosed methods and apparatus can actually count and size particles to identify the extent of degradation of the dispersion or suspension - i.e., the rate of particle agglomeration - before and after the application of stress.

The Applicants' disclosed determination of the stability can be based on continuously regulated and deliberately accelerated agglomeration of droplets or particles brought about by the systematic application of a small "perturbation" in the composition of the liquid medium of the suspension (e.g., page 33, lines 16-20). This perturbation can consist of deliberate, calibrated changes in pH, addition of screening salt or addition of adsorbing electrolyte.

A normal rate of degradation of a particulate-based system in effect defines the "stability" of the system (e.g., page 3, lines 11-17). Here, "stability" refers to the ability of the components in a solution to substantially remain unaggregated, recognizing that in thermodynamically unstable systems, all relevant "systems" will eventually aggregate and separate, thus reverting to their original phases. The disclosed methods and apparatus can accelerate this process to discover an underlying rate of agglomeration, or stability, of a sample and evaluate the "robustness," quality or stability of the emulsion or dispersion system by "stressing" it in a relatively "gentle" manner, such that the underlying character of the system is presumed to remain essentially unchanged (e.g., page 25, lines 4-9). For example, if the emulsion in one lot exhibits a significant increase in particle agglomeration after a given elapsed time for a given level of stress factor (i.e., pH, salt or electrolyte concentration), but another lot of identical composition exhibits a negligible change in agglomeration after the same elapsed time under the same "stress" conditions, the

difference in stability can be used to identify a potential processing or manufacturing flaw, such that the stability cannot be consistently maintained (e.g., page 47, lines 1-15). The Applicants' disclosed methods and apparatus can be applied to a number of different dispersions of varying composition and use to probe the quality and consistency of the dispersion system and the associated processing or manufacturing conditions.

For example, Applicants have disclosed experimental data for a vegetable oil-in-water emulsion indicative of significant droplet agglomeration typically occurring approximately 20 hours after the addition of certain mixed ionic species (e.g., page 61, lines 16-18). With application of appropriate stress factors, e.g., by decreasing the pH (adding acid) or by adding (screening) salt, the time needed to arrive at similar levels of droplet agglomeration is greatly reduced. In this way, it becomes possible to identify a relatively unstable emulsion (i.e., containing the added mixed ionic species) compared to a significantly more stable emulsion (not containing the mixed ionic species) after a much shorter time than would normally be required. Similarly, the evaluations of milk samples over their producer-assigned shelf lives, assesses the presumed validation procedures first used to establish acceptable period of use of the product (e.g., page 48, lines 1-20). These exemplary procedures can accelerate assessment of emulsion stability to identify, e.g., unforeseen processing or manufacturing flaws so as to improve the quality of the finished dispersion product, and serve to demonstrate an exemplary application of the presently claimed invention.

The foregoing features are broadly encompassed by claims 1 and 47, which recite, among other features, applying a stress factor to said sample to reduce a

height of an interparticle potential energy barrier so as to accelerate the onset of significant particle agglomeration, and detecting an increase in said particle agglomeration.

The Garver et al. patent does not teach or suggest applying a stress factor to a sample to reduce a height of an interparticle potential energy barrier so as to accelerate the onset of significant particle agglomeration as recited in claims 1 and 47. The Examiner impermissibly uses hindsight based on the disclosures in the present application to construe the Garver et al. patent.

Although the Garver et al. patent discloses a change in temperature, this temperature change is not applied as a "stress factor" as claimed. The Garver et al. patent is based on a phase transition selectively induced by a temperature change, i.e., influencing the physical state of certain colloidal particle components in a liquid sample, but not others (abstract). The Garver et al. patent does not disclose using a stress factor, such as a change in pH, added salt or added adsorbing electrolyte. The use of temperature as disclosed in the Garver et al. patent does not constitute application of a stress factor because it can not be used to determine stability of a sample. Garvers' use of temperature does not accelerate an onset of significant particle agglomeration in a manner which permits stability of a sample to be determined (e.g., Garvers' use of temperature does not provide an onset of significant particle agglomeration in a manner which is slow enough to be measurable as a function of elapsed time).

The Garver et al. patent does not teach or suggest reducing a height of an interparticle potential energy barrier so as to accelerate the onset of significant particle agglomeration. A temperature-induced phase transition of the Garver et al.

patent is an "all-or-nothing" physical mechanism which is not intended to "gently" accelerate the occurrence of significant particle agglomeration of a chosen colloidal species of particles.

The "stability" referenced by Garver et al is very different from the claimed determination of the stability of a sample. The word "stability" of the Garver et al. patent refers to whether the sample component of interest, "colloidal pitch or wood resin", remains mostly unaggregated in suspension or effectively changes physical state, due to massive agglomeration resulting from a temperature dependent phase transition (abstract). Because this transformation is based on a phase transition, one would expect this agglomeration phenomenon to be reversible with temperature. By implication, the solubility or insolubility of a particular colloidal component is typically reversible.

An objective of the Garver et al. patent is to distinguish a first, undesirable "colloidal pitch" particle component from other colloidal components, so as to be able to apply chemical and/or other means to eliminate or reduce the concentration of this first, undesirable component (e.g., col. 3, lines 5-7). In other words, the Garver et al. patent relates to a method of identifying the presence of an undesirable component or the equivalent of a "contaminant", not an intended component of the system. The Garver et al. patent discloses colloidal particles consisting of "colloidal pitch or wood resin" particles. The Garver et al. patent discloses "In the area of pulp and paper manufacture, the maintenance of a level of stability and removal of colloidal pitch is an important objective in the wet-end chemistry programs" (col. 2, line 21). The Garver et al. patent further discloses "Chemical and physical methods of controlling

pitch may be monitored... There is no colloidal pitch measurement available on-line ...” (col. 2, lines 45 and 60).

Thus, the Garver et al. patent relates to detecting and measuring (semi-quantitatively) the existence of this “colloidal pitch” component or contaminant. The colloidal pitch or wood resin particles are different from other kinds of colloidal particles, such as talc, clay and carbon black that are the intended components present in the “sample”.

The Garver et al. patent discloses rapid determination of an amount of colloidal pitch (e.g., col. 3, lines 8-10). By “amount” they mean relative amount. Rather than controlling chemically the concentration of undesirable colloidal pitch, the Garver et al. patent discloses varying the temperature to identify the presence of a colloidal pitch in pulp. The Garver et al. patent discloses subjecting multi-component samples to a change in temperature, but nowhere does it teach or suggest applying a “stress factor” to reduce a height of an interparticle potential energy barrier so as to accelerate the onset of significant particle agglomeration.

The Examiner asserts at numbered paragraph 4 of the Office Action that the Garver et al. patent teaches “a measure of the stability of the dispersion with respect to temperature.” This assertion is traversed. The change in temperature disclosed in the Garver et al. patent induces a phase transition (col. 1, line 9). The resulting phase change allows for the selective semi-quantitative detection of a particular colloidal pitch in a background of at least one other, different, colloidal particle component, which responds differently (i.e., relatively little) to the change in temperature. The temperature change disclosed in the Garver et al. patent is not used to investigate the stability of the sample, or lack thereof. Rather, the sample is

deliberately caused, by initiation of a phase transition, to change its physical state and thus effectively become significantly “unstable” with respect to the colloidal component of interest (e.g., col. 1, lines 10-11). This temperature-induced instability does not constitute acceleration of the onset of significant particle agglomeration for detecting an increase in said particle agglomeration. In contrast to a change in the physical state of a dispersion, Applicants' disclosed introduction of stress can be characterized as “mild perturbations” that push the system to its limits of stability.

The Garver et al. patent teaches away from detecting a rate of increase in the particle agglomeration. The Applicants' disclosed methods and apparatus can actually count and size particles to identify the extent of stability degradation. However, the Garver et al. patent discloses, “The laser method, known as a pitch counter, requires expensive and specialized instrumentation that is not easily adopted to analysis in an industrial setting” (col. 3, lines 1-4) which, in effect, separates the Garver patent as a novel alternative to counting particles.

Applicants have disclosed in the Description of the Related Art the particular disadvantages of prior attempts to use temperature to accelerate stability testing of emulsions. The efforts of Kwan et al, Faure et al, Garver et al and Yoon et al, summarized by Vadas, were cited (e.g., page 17, line 12 – page 19, line 6). The limitations and possible undesirable effects of applying thermal variations were disclosed: “Depending on the complexity of the phase diagram, these increases in temperature may achieve the undesirable result of converting the emulsion or dispersion into a significantly different system, physically speaking, including having a significantly different PSD [particle size distribution]. This possible behavior is in sharp contrast to using the variable of temperature for perturbing the effectiveness of

the net repulsive interaction between neighboring charged particles or droplets, while the character of the emulsion or dispersion is presumed to remain essentially unchanged" (e.g., page 19, line 21- page 20, line 6). Garver et al teach away from particle counting, the Applicants embrace for use in determining stability.

The Examiner asserts at numbered paragraph 4 of the Office Action, "It is inherent in the method taught by Garver et al that the instability of the colloid sample analyzed is manifested by particle agglomeration due to the reduction in the height of the potential energy barrier between the particles since Garver et al teach that the particles in the colloid sample undergo phase transition due to the change in the temperature applied, and the measurements of light attenuation and light scattering serve to give an overall particle distribution of colloidal components (i.e. agglomerated particles) therein." This assertion is respectfully traversed.

The asserted "instability" of Garver et al. refers to a phase transition brought about by a change in temperature disclosed by the Garver et al. patent (e.g., col. 1, lines 47-57). Molecules of a particular colloidal component undergo a shift in physical state - i.e., from largely monomeric to heavily agglomerated - following a shift in temperature. Stability in this context is only relative to temperature for a given system. Depending on the desired state, the system can be classified as "stable" for a fixed temperature. The Garver et al. patent induces a particular, desired phase transition – a specific, temperature-induced change in the location of the system within a typically complex phase diagram. The Garver et al. patent discloses changing one physical state to another within the phase diagram of the system, but the Garver et al. patent does not teach or suggest lowering the energy barrier in deliberate increments. The Garver et al. patent does not teach or suggest

reducing, systematically or otherwise, the potential energy barriers that describe the system, as their method changes the physical state of the system. The Applicants clearly stay within the stability domain of the original system.

The Garver et al. patent does not employ a deliberate "gentle destabilization" of a system to gain any insight into the underlying stability, or lack thereof, of the starting sample. Rather, the Garver et al. patent relates to a reversible temperature process that does not relate to the claimed determination of a stability of a sample. For at least these reasons, the Garver et al. patent does not teach or suggest the claimed features.

The Nicoli et al. and The Frieberg et al. Publications

On page 4 of the Office Action, independent claims 1, 40 and 47, along with various dependant claims, are rejected under 35 U.S.C. §102(b) as being anticipated by Nicoli et al., "Particle size analysis of colloidal suspensions by SPOS compared to DLS: A sensitive indicator of quality and stability," American Laboratory, vol. 33(1), January 2001, pp. 32-39). On page 6 of the Office Action, independent claim 40, along with various dependant claims, are rejected as being unpatentable over the Nicoli et al. article. On page 7 of the Office Action, various dependant claims are rejected as being unpatentable over the Nicoli et al. article in view of Friberg et al. "Theory of Emulsions," Pharmaceutical Dosage Forms: Disperse Systems, Lieberman et al. (eds.), Vol. 1, 1988, page 66. These rejections are respectfully traversed.

The Applicants have disclosed in the specification applying "stress" to a sample. The resulting accelerated time behavior of the growth in particle agglomeration can then reveal the underlying degree of stability (or lack thereof) of

the sample (e.g., page 37, lines 8-20). The sample at the outset usually does not possess significant particle agglomeration as indicated by an extensive PSD tail of "over-size" particles (e.g., page 38, lines 1-3). Samples which otherwise appear to be similar and substantially equal with respect to the extent of particle agglomeration (as revealed by their PSD tails) can now be distinguished as "more stable" and "less stable" (and to what extent) through the systematic application of appropriate stress factors at appropriate stress levels.

The concept of "stability", as disclosed by the Applicants, includes the concepts of elapsed time (i.e., of the dynamics of particle agglomeration) and degree of immunity to destabilizing influences (e.g., page 37, lines 20-22). Applicants have disclosed that an inter-particle repulsive energy barrier height may be lowered by a given amount due to a change in pH or addition of a screening salt or adsorbing electrolyte. The rate of agglomeration determines the degree to which the system can be described as "stable". The stability is quantitatively determined based on determined rates of agglomeration of suspension or dispersion systems by accelerating the agglomeration process. While two samples may be suspected of differing in "stability", they will typically not reveal their differences with respect to agglomeration until an excessively long time has elapsed.

Applicants have disclosed applying a level, or series of levels, of a stress factor to the system and making a series of measurements of the PSD tail as a function of elapsed time for each stress level (e.g., page 35, lines 7-18). Subsequently, the percentage of the dispersed phase (PDP) implicated in the PSD tail is measured. From one or more derivatives of the PDP with respect to time

and/or stress level, the underlying stability of the system can be estimated quantitatively.

The foregoing features are broadly encompassed by claims 1 and 47, which recite, among other features, applying a stress factor to said sample to reduce a height of an interparticle potential energy barrier so as to accelerate the onset of significant particle agglomeration, and detecting an increase in the rate of said particle agglomeration; and claim 40, which recite, among other features, applying a stress factor to said sample to reduce the height of said interparticle potential energy barrier so as to accelerate agglomeration of said particles, and detecting the increase in said agglomeration using sensitive, quantitative means for determining the extent to which said sample has become less stable by producing a particle size distribution (PSD) showing the concentration of particles as a function of size over a range of particle sizes larger than normal (i.e., unaggregated) and a tail of large-diameter outlier particles larger than said normal particle sizes indicative of the increase in agglomeration.

The Nicoli et al. article does not determine the stability of samples in a manner as presently claimed. The Nicoli et al. article describes two concepts. First, the quality of a sample can often be ascertained by determining the percentage of particles that populate the large-diameter "tail" of the PSD. Second, this tail can indeed be quantified using the sensitive technique of SPOS.

The Nicoli et al. article does not describe determining the rate of particle agglomeration increases in a given sample due to a decrease in barrier height. Isolated "snapshots" of the PSD, relatively widely separated in time, such as those shown in the article for a fat emulsion and a silica CMP slurry, do not teach or

suggest quantitative measure of the stability of the sample with respect to particle agglomeration (e.g., Figs. 4-6). There is only a "before" and "after" snapshot of the PSD (or series of isolated "after" snapshots, in the case of the fat emulsion).

The Nicoli et al. article does not describe using graduated, systematic stressing of a sample and subsequent required measurement as a function of time and/or stress level. It is the current quality of the sample, indicated by the extent of particle agglomeration, that can be assessed by SPOS tail measurement and not the stability per se (e.g., col. 2, page 38). The measurements shown and discussed are isolated snapshots, obtained at relatively widely separated times, not measured, smoothly evolving trends (allowing determination of slopes of computed PDP values as a function of time and/or applied stress level) that have been caused to occur by deliberate application of stress levels.

The SPOS method disclosed in the Nicoli et al. article does not determine a quantitative stability of the CMP slurry samples. The word "stability" as used in the article connotes quality of characteristics and/or performance of the sample, rather than constancy, or "stability," of the latter over time. As disclosed in the Nicoli et al. article, in the case of the CMP slurry samples, the concentration and size of the outlier particles that define the upper tail of the PSD serve as a quantitative indicator of the quality of the slurry. Second, known physical mechanisms are responsible for growth in the PSD tail for these slurries. These abnormally large particles are usually aggregates of the smaller primaries, typically produced by mechanical stress or thermal/pH shock of the slurry (e.g., last column of page 34). The article disclosure relates to the quality of the slurry, and not a quantitative stability of the CMP slurry samples.

The Examiner states at paragraph 8, page 6, of the Office Action, "Nicoli et al fail to teach that changing the pH level or adding electrolyte to a colloidal suspension serves to change or reduce the net charge on the surfaces of the particles in the suspension," but the Examiner asserts, "However, such a phenomenon would have been obvious to one of ordinary skill in the art at the time of the instant invention since Nicoli et al teach that the stress factors such as pH shock and addition of electrolyte to a colloidal suspension serve to change and reduce the electrostatic repulsion between the particles, thus indicating a change or reduction of the net charge on the surfaces of the particles."

Applicants respectfully traverse the foregoing Examiner's conclusion. It would not have been obvious to deliberately and controllably apply a stress factor to a sample to reduce a height of an interparticle potential energy barrier so as to accelerate the onset of significant particle agglomeration. For example, none of the well-recognized prior art references cited teaches this concept. The Nicoli et al article establishes only the ability to ascertain the present quality of a given particle suspension using the SPOS technique, but does not describe an ability to probe and subsequently discover the underlying stability of that suspension.

The Examiner states at paragraph 8, page 6, of the Office Action, that "Nicoli et al also fail to teach of applying the stress factors to a colloidal suspension in increments at spaced time intervals resulting in increasingly higher stress levels, or of applying different levels of stress factor to different batches of the same colloidal suspension," but the Examiner asserts "However, these steps would have been obvious to one of ordinary skill in the art in order to analyze and determine what level of stress factor is required to cause a colloidal suspension to become unstable, and

how long/what level of the stress factor must be applied to the colloidal suspension in order to render it unstable." The Examiner's conclusion is respectfully traversed.

As claimed, there is no single time ("how long") or single "level of the stress factor" that is relevant to the determination of underlying system stability using the methods taught. Indeed, there is no single level of stress that renders the system of interest "unstable". Rather, as disclosed by the Applicants, the calibrated application of one or more stress factors results in an accelerated, but continuous ("smooth"), rate of particle/droplet agglomeration. The stress levels were sufficiently modest that after significant elapsed time the systems remained relatively stable, in the sense that the percentage of particles implicated in the PSD tails (as revealed by the calculated PDP values) remained relatively small.

By contrast, the "before" and "after" results shown and discussed in the Nicoli et al article basically show suspensions that contain either relatively small populations of large agglomerates or very large populations, following substantial destabilization. The Nicoli et al. article does not describe levels of stress applied to the system, and does not describe accelerated stress testing of particle suspensions.

The Examiner states at paragraph 8, page 7, of the Office Action that "Nicoli et al also fail to teach of calculating the percentage of the dispersed phase (PDP) in the colloidal suspension analyzed from the measured particle size distribution," but the Examiner concludes, "However, such a step would have been obvious to one of ordinary skill in the art in order to obtain a measure of the stability of the suspension since the greater the percentage of dispersed particles in the suspension, the greater the stability and vice-versa." Applicants respectfully traverse the Examiner's conclusion.

Applicants have disclosed that the percentage of dispersed particles in the suspension is fixed for a given sample, regardless of the extent of particle agglomeration contained therein. This is simply the sum total of all the particles, regardless of their state of agglomeration, expressed as a volume (or, equivalently, mass) percentage. The PDP level, or value, is not correlated per se to the stability of the sample. The extent of the agglomerate PSD tail, as measured by the PDP, can be used to infer the quality of a sample, but not its stability. The latter can be inferred only by determining the rate of change of the PDP with elapsed time (i.e., for a given applied stress level) or the rate of change of the PDP with increasing stress level (i.e., for a given elapsed time). The Nicoli et al. article does not describe changes in the PDP with time for given applied stress levels or how much the PDP changes with rising stress levels for given elapsed times in relation to the degree of underlying stability of a given emulsion to dispersion.

In numbered paragraph 9 of the Office Action, the Examiner asserts: "Friberg et al teach that the addition of an electrolyte or salt such as sodium chloride to an emulsion causes a reduction in the electric repulsion potential of the particles in the emulsion, and a resulting reduction in the barrier height between the particles. This change with salt concentration results in a loss of stability in the emulsion due to the agglomeration of the particles therein. Friberg et al teach that the change from a stable emulsion to an unstable one takes place at a well-defined salt concentration." The Examiner's conclusions are traversed.

The Friberg et al. document does not relate to the claimed stability of an emulsion or dispersion. Contrary to the assertion ascribed to the Friberg et al. document, there is no "well-defined salt concentration" that converts a suspension

from being "stable" to being "unstable". There are, in effect, a huge number of emulsions or dispersions (of the same composition) having varying degrees of stability, characterized by a huge number of rates of particle agglomeration, rather than simply a "stable" or "unstable" system, as suggested by the Friberg et al. document. The Friberg et al. document does not teach or suggest quantitative determination of different rates of agglomeration to ascertain the stability of two or more examples of an emulsion or dispersion system by perturbing the same through a deliberate application of stress factors.

The Friberg et al. document is directed to an entirely different problem of "switch" of an emulsion between "stable" and "unstable" through the application of a "well-defined salt concentration". The Friberg et al. document did not contemplate a controlled application of stress levels to emulsion systems having different underlying stability, or rates of particle agglomeration. Accordingly, the Friberg et al. document is not directed to determining the stability of emulsions and other colloidal dispersions as claimed. For at least these reasons, the Friberg et al. document does not cure the deficiencies of the Nicoli et al. article.

Conclusion

As such, Applicant's independent claims 1, 40 and 47 are allowable. All objections and rejections raised in the Office Action having been addressed, it is

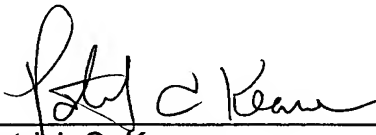
respectfully submitted that the application is in condition for allowance and a Notice of Allowance is respectfully solicited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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By: _____



Patrick C. Keane
Registration No. 32,858

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620